

KENTUCKY BOARD OF MEDICAL LICENSURE

201 KAR 9:260 Summary

***Please note this is a summary of 201 KAR 9:260. Physicians should review and refer to the actual regulation, which is available at the Board's website, www.kbml.ky.gov. This summary does not replace 201 KAR 9:260 and should not be considered legal advice or a legal opinion.**

Section 1 – Exceptions to Standards in 201 KAR 9:260 – Prescribing Controlled Substances

- Where part of the patient's hospice or end-of-life treatment;
- If patient admitted to a hospital as an inpatient, outpatient, or observation patient;
- Cancer patients or pain related to cancer treatment;
- Patients in long-term care facilities;
- During any period of disaster or mass casualties;
- In a single dose prescribed/dispensed to relieve anxiety, pain, or discomfort for diagnostic test or procedure; and
- Any Scheduled V Controlled Substance.

Section 2 – Standards for Documentation

- If unable to conform to the standards or if a determination is made that it is not appropriate to comply:
 - Only prescribe/ dispense to patient when the record appropriately justifies the action.

Section 3 – Initial Prescribing to Treat Non-Cancer Pain - Acute

- History & physical appropriate to condition;
- KASPER review;
- Avoid prescribing more than necessary to treat condition;
- Patient education/Counseling on Controlled Substances.

Section 4 – Commencement of Long-term Prescribing (AFTER 90 Days) to Treat Non-Cancer Pain

- Different licensed practitioners working in same practice location may perform tasks to meet the required standards so long as in their scope;
- Comprehensive history to include:
 - History of substance abuse/treatment for patient & history of abuse for first degree relatives;
 - Past family history of relevant illness & Psychosocial history;
 - Appropriate Physical Exam to support long-term use of controlled substances;
 - Baseline Assessments to establish & monitor treatment plan;
 - Obtain Prior Medical Records, if needed to justify continued prescribing;
- Formulate Working Diagnosis;
 - Refer if necessary to formulate a working diagnosis;
 - Only prescribe if medically indicated & appropriate if no working diagnosis can be established despite referral;
- Develop and document treatment plan if improvement is medically expected;
- Baseline drug screen – do not prescribe if medication is determined being used/likely to be used for other than medicinal purpose;
- Screen for other conditions that may impact treatment or necessitate a referral;
- Diversion risk – if patient determined to be high risk – prescribing agreement;
- Written Informed Consent;
- Attempt trial of other modalities and lower doses, or document a previous attempt by another;
- KASPER Review.

Section 5 – Continued Long-Term Prescribing Non-Cancer Pain in Patients

- Ensure patient is seen monthly, until titrated to appropriate level;
- At appropriate intervals:
 - Update H&P as necessary;
 - Perform Measurable Exams; and
 - Evaluate and update working diagnosis and treatment plan;
- Annual Preventive Health Screening - conduct or ensure is done;
- KASPER review every 3 months; More frequent or immediately if indicated;
- Notify other practitioners if you suspect “doctor shopping”;
- Random pill counts if appropriate;
- Random Drug Screens appropriate to the drug prescribed and the patient’s condition and if the patient is noncompliant, discontinue prescribing, do a controlled taper or make referral;
- Consultative Assistance – as appropriate;
- Significant Risk of Diversion – discontinue prescribing or document /justify use in record;
- No Significant Improvement Where Expected – obtain consultative assistance;
- Mood, Anxiety or Psychotic Disorders – obtain psychiatric consult if appropriate;
- Document Treatment or Refer to Addiction Management – no improvement where medically expected; significant adverse effects; or patient exhibits inappropriate or behavior/ diversion;
- Breakthrough Pain – Identify triggers – attempt non-controlled substances or if adding controlled substances, take steps to minimize likelihood of improper/illegal use;

Section 6 - Prescribing and Dispensing of Controlled Substances in an Emergency Room Department

- Comply with standards for initial prescribing for pain and other conditions;
- Physicians are strongly discouraged and shall not routinely:
 - Administer intravenous controlled substances for relief of acute exacerbations of chronic pain, unless it is the only medically appropriate means of delivery;
 - Provide replacement prescriptions that were lost, destroyed, or stolen;
 - Provide replacement doses of methadone, suboxone, or subutex;
 - Prescribe long-acting, controlled release medication, or replacement doses of such medication;
 - Administer Meperidine to the patient;
 - Prescribe or dispense more than minimum amount necessary to treat condition until patient can be seen by their physician, with no refills. If the prescribing exceeds 7 days, the patient record must justify the amount prescribed.

Section 7 – Treatment of Other Conditions – Not Pain**Initial Prescribing to Treat Other Conditions**

- History and Physical;
- KASPER Review ;
- If a request by established patient for a script to deal with non-recurring single episode or event involving anxiety/depression:
 - KASPER review
 - Decide to prescribe with or w/o a personal encounter;
 - Prescribe minimum amount necessary;

Subsequent/Ongoing Prescribing to Treat Other Conditions

- Conform to standards of acceptable & prevailing medical practice for that drug and condition

Section 8 – Responsibility to Educate Patients - See Regulation

Section 9 – Additional Standards for Prescribing or Dispensing Schedule II Controlled Substances or Schedule III Controlled Substances Containing Hydrocodone – AS REQUIRED BY HB 217

- **In addition to the other standards in this regulation:**
 - Query KASPER
 - Make a written plan;
 - Obtain written consent;
- Prescribing/ dispensing additional amounts for same medical complaint/symptoms:
 - Review, at reasonable intervals the plan of care;
 - Provide to patient any new information about the treatment; and
 - Modify or terminate the treatment as appropriate;
- If the course of treatment goes beyond 3 months:
 - Query KASPER once every 3 months;
- Keep accurate, readily accessible and complete medical records;
- **Exemptions from additional standards involving Schedule II & III w/Hydrocodone:**
 - Prescribing/ dispensing for administration to a patient admitted to a hospital/long-term care facility if the facility/ practitioner puts a KASPER in the chart within 12 hours;
 - Prescribing or dispensing:
 - No more than a 14 day supply following an operative or invasive procedure/ delivery – longer supply requires compliance w/additional standards;
 - As part of patient’s hospice or end-of –life treatment;
 - For treatment of pain associated w/ cancer or cancer treatment;
 - A substitute prescription within 7 days of the initial prescription so long as any refills to the initial prescription are cancelled and the patient is required to dispose of any unused medication;
 - To the same patient for the same condition by a partner or other cover arrangement within 90 days of the initial prescription; or
 - To an IRB approved research subject enrolled in blind study.

Section 10 – Violations – See Regulation

Additional Resources for 201 KAR 9:260

- To review a copy of the actual regulation, you can visit the Board’s website, http://www.kbml.ky.gov/NR/rdonlyres/41B554D0-DB32-4A23-8923-E8ACAB913CF0/0/201_009_260.pdf. Physicians should review the regulations themselves, as the Board’s summary is not comprehensive or intended to take the place of reading the regulations.
- **KMA Summary** - for a more detailed summary of the controlled substance regulations, the Board directs your attention to one currently available on the Kentucky Medical Association website. To access the summary, simply visit <https://www.kyma.org/content.asp> and look for the headline “KMA Publishes Summary of Revised KBML/OIG Controlled Substance Regulations”.